

Handwritten initials



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/988,496 | 11/20/2001 | David J. Anderson | CTCH-P01-007 | 8536 |

28120 7590 03/30/2005
FISH & NEAVE IP GROUP
ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,496

Applicant(s)

ANDERSON ET AL.

Examiner

Joseph T. Woitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-40, 73-86, 89, 90, 93, 95 and 96 is/are pending in the application.
4a) Of the above claim(s) 32-38, 40, 74-86 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 39, 73, ~~86~~, 89, 90, 93, 95 and 96 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Please note that the Examiner of record and art unit has changed. The Examiner of record is now **Joseph T. Voitach** and the group art unit is now **1632**.

Applicants' after final amendment filed January 31, 2005, has been received and entered. As indicated in Applicants' comments claims previously submitted in the amendment filed May 7, 2004 have not been considered. Prosecution is hereby re-open to fully consider the claim amendments filed May 7, 2004.

Applicants' amendment filed May 7, 2004 has been received and entered. Claims 1-31, 41-72 have been cancelled. Claims 87-96 have been added.

Applicants after final amendment filed January 31, 2005, has been received and entered. Claims 39, and 93 have been amended. Claims 87, 88, 91, 92 and 94 have been canceled. Claims 32-40, 73-86, 89, 90, 93, 95 and 96 are pending.

Election/Restriction

Applicant's election with traverse of Group V in the reply filed on October 3, 2003 was acknowledged. No new arguments in traverse of the requirement have been provided by Applicants.

The requirement is still deemed proper and is made **FINAL**.

Claims 32-40, 73-86, 89, 90, 93, 95 and 96 are pending. Claims 32-38 and 40 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed October 3, 2003. Claims 74-86 have been withdrawn from consideration as being directed to a non-elected invention for reasons of record set forth in the previous office action of January 7, 2004. See 37 CFR 1.142(b) and

Art Unit: 1632

MPEP § 821.03. Newly added claims 87-96 depend on claim 39, and are encompassed by the elected invention. Claim 39, 73 and 89, 90, 93, 95 and 96 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39 and 73 stand rejected and newly added claims 89, 90, 95 and 96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a method of assessing effect of an agent on arterial smooth muscle cells wherein the agent binds to a cell-surface protein selected from the group consisting of an Ephrin family and an Eph family receptor.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. When the claims are analyzed in light of the specification, instant invention recites a genus, an agent that binds to a cell-surface protein selected from the group consisting of an Ephrin family and an Eph family receptor. However, the specification does not teach what is the complete structure of any agent. Except for disclosing that an agent or modulator could be any compound, the specification does not teach what would be the structure of a species of the genus.

Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the only other identifying characteristic is that the agent

Art Unit: 1632

binds to a cell-surface protein selected from the group consisting of an Ephrin family and an Eph family receptor. However, the specification does not disclose any identifying characteristic as to how an artisan would have differentiated one agent from another agent. Additionally, the claims recite any member of Ephrin or Eph family, however, the specification only teaches EphrinB2 and EphB4. It is noted that arterial smooth muscle cells express EphrinB2 and EphB4 (Shin et al. Developmental Biology 230:139-150, 2001). Neither the specification nor the art of record teaches any other Ephrin or Eph proteins expressed by arterial smooth muscle cells. In other words, there is no evidence of record that the Applicants had possession of any other arterial smooth muscle cells that expressed any other Ephrin or Eph than EphrinB2 and EphB4. With respect to newly added claims, only claims 87, 88, 92 and 94 specifically set forth EphrinB2 and EphB4

Accordingly, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that the applicant is in possession of the broad genus of the modulators or agents at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

Claims 39, 73 and 89, 90, 93, 95 and 96 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, the amendment to recite "wherein said agent binds Ephrin B2" is considered new matter. Applicants point to several portions of the specification for support of the amendment, however none of the cited portions or upon review of entire specification provide support that the agent being tested uniquely binds to the Ephrin family ligand or Eph family receptor or more specifically to Ephrin B2. With the specific portions of the

Art Unit: 1632

specification cited in the specification: page 19 deals with the isolation of Ephrin/Eph; page 25 deals with agents in general; page 32 deals with a means to provide a vehicle and page 36 deals specifically with compounds of known function namely agonist and antagonist. None of the cited portions of the specification support the general concept that the agent being tested must bind anything. On page 25 that details how agents can be made, there is no teaching that the compounds made must be constructed such that they bind anything, to the contrary it appears that any agent can be tested.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 39, 73 and 87-96 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described. As noted above, there is no literal nor figurative support for the type of agent contemplated. It appears to be contrary to the method itself since it is a method to assessing the affect of the agent. In light of the guidance of the specification, no prior knowledge of the agent is required. Moreover, there is no guidance in the present specification to provide the genus of agents for use in the claimed methods.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the the time the application was filed...If a claim is

Art Unit: 1632

amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39 and 73 stand rejected and newly added claims 89, 90, 93, 95 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the claims are unclear because the antecedent basis for the wherein clause indicating that the agent binds to a cell-surface protein is not sufficiently set forth in the claims. Previously the claims encompassed adding any type of agent and looking at the affect. With the new amendment, it is unclear if prior knowledge of the agent is required to practice the method, i.e. that the agent binds, or if the effect seen is due to the binding. The claims are vague and indefinite because it is unclear as to whether the recited agent binds to an Ephrin family or an Eph family protein present on an arterial smooth muscle cell or on any other cell, or an effect is an indicator of binding.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1632

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39 and 73 rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto *et al.* (Stroke 29:1188-1193, 1998) is withdrawn.

Claims 39 and 73 rejected under 35 U.S.C. 102(e) as being anticipated by Haber *et al.* (US Patent 6,440,954 B1, 8-27-2002, effective filing date 8-18-1997) is withdrawn.

Claims 39 and 73 rejected under 35 U.S.C. 102(e) as being anticipated by Olson *et al.* (US Patent 6,015,711, 1-8-2000, filing date 7-28-1998) is withdrawn.

Applicants note that none of the cited references teach Ephrin 2B, nor that any of the compounds tested would bind to Ephrin B2. Applicants' arguments have been fully considered, and found persuasive. Specifically, upon review of the cited reference, Examiner agrees that none of the compounds tested appear to bind to Ephrin B2 as required by the instant claims. The references were applied when the claims read broadly on testing any compound on smooth muscle cells. It is noted however that it would be maintained that smooth muscle cells do inherently express Ephrin B2, and that testing compounds in general on smooth muscle cells would anticipate the use of agents that do not specifically bind Ephrine B2.

Art Unit: 1632

Conclusion

No claim is allowed. The claims are free of the art of record, because the prior art fails to teach Ephrin B2, in particular a range of agents that specifically bind to it as required by the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach
AUG 32